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FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) \$0.00

Complete if Known

Application Number	09/972,225
Filing Date	10/04/2001
First Named Inventor	Dorros
Examiner Name	RODRIGUEZ, CRIS L.
Art Unit	3763
Attorney Docket No.	AMS-011A

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 790	2001 395	Utility filing fee	
1002 350	2002 175	Design filing fee	
1003 550	2003 275	Plant filing fee	
1004 790	2004 395	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
20** =			0.00
Independent Claims	- 3** =		0.00
Multiple Dependent			0.00

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 88	2201 44	Independent claims in excess of 3
1203 300	2203 150	Multiple dependent claim, if not paid
1204 88	2204 44	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 430	2252 215	Extension for reply within second month	
1253 980	2253 490	Extension for reply within third month	
1254 1,530	2254 765	Extension for reply within fourth month	
1255 2,080	2255 1,040	Extension for reply within fifth month	
1401 340	2401 170	Notice of Appeal	
1402 340	2402 170	Filing a brief in support of an appeal	
1403 300	2403 150	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,370	2501 685	Utility issue fee (or reissue)	
1502 490	2502 245	Design issue fee	
1503 660	2503 330	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))	
1801 790	2801 395	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 0.00

SUBMITTED BY

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AMS-011A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants : Gerald NMI Dorros et al.
Serial No. : 09/972,225 Confirmation No. 4566
Filed : October 4, 2001
For : APPARATUS AND METHODS FOR TREATING A
STROKE AND CONTROLLING CEREBRAL FLOW
CHARACTERISTICS
Group Art Unit : 3763
Examiner : Cris L. Rodriguez

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APPELLANT'S REPLY BRIEF

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Introduction

The Appeal Brief filed April 16, 2004 explains why Barbut '057 and Barbut '370, relied upon by the Examiner in the Final Rejection dated September 16, 2003 do not render obvious the applicant's claimed invention. The Examiner's Answer substantially repeats the rejections set forth in the Final Rejection.*

The Examiner's Answer does not respond to the arguments set forth in the Appeal Brief, but instead either mischaracterizes those arguments as being directed to functional limitations or completely ignores them. The devices disclosed in Barbut '057 do not possess the structural features recited in appellant's claims. Moreover, the device in the '057 patent would be inoperative if used in accordance with the functional recitations of appellant's claims. Finally, the Examiner's Answer also provides no hint as to why one there would have been motivation to modify Barbut '057 in view of the totally different structure and purpose of Barbut '370.

II. Appellants' Claimed Invention Is Structurally Different Than Barbut '057

The Examiner's Answer continues to maintain that Barbut '057 shows the invention set forth in claim 1, except that the catheter is inserted via the descending aorta. Appellants disagree.

* The arguments set forth in the Examiner's Answer are subtly different. For example, the Final rejection contended that it would have been obvious to "substitute" catheter 12 of Barbut '370 for catheter 1 of Barbut '057; the Examiner's Answer now suggests that it would have been obvious to provide such a catheter for use in the system of Barbut '057. Appellants do not believe that these differences substantially change the nature of the rejections, nor render less determinative the arguments set forth in appellants' Opening Brief.

Appellants' opening brief explains in detail that Barbut '057 is directed, not to manipulating flow in a patient ongoing removal of a cerebral blockage, but instead to the entirely different problem of perfusing the brain of a person in cardiac arrest. Opening Brief at 8-11. In appellants' inventive system, the occlusive element is used to occlude antegrade flow in a carotid artery, and so that retrograde flow can be established in the carotid artery to aspirate emboli. So as to ensure that emboli are funneled into the catheter, both independent claims 1 and 26 recite that the structural limitation that "the **occlusive element** [has] an opening that communicates with the lumen."

The Examiner's Answer argues that "Figure 3 shows openings in the catheter in fluid communication with the lumen." The openings in Figure 3, however, are located in the catheter body, **not the occlusive element**. This is not a minor distinction. In Barbut '057 the objective is simply to move blood from line 20 to line 10, so it is immaterial where the opening is located. As described in appellants' opening brief at page 11, in the present invention the opening is disposed in the occlusive element so that emboli cannot collect in a stagnant space proximal to the opening. That is exactly what would happen if the catheters in Figure 3 of Barbut were to be used for emboli removal - rendering the system inoperative to meet the functional recitations of the claim.

Moreover, as argued in appellants' opening brief, there is no teaching that catheter 1 in Barbut '057 be constructed of a length to permit insertion via the descending aorta. Although the Examiner's Answer continues to assert it would have been obvious to modify Barbut '057 as in Barbut '370, the Answer provides no rationale why one of ordinary skill would have been motivated to so modify Barbut '057.

**III. There is No Motivation to Modify
Barbut '057 According to Barbut '370**

To establish a *prima facie* case of obviousness, three basic criteria must be met:

"First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined), must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure." M.P.E.P. § 2142.

Independent claims 1 and 26 have been rejected over the combination of Barbut '057 and Barbut '370. Because modification of the Barbut '057 is required to support these rejections, appropriate motivation to make the proposed modification must be identified to establish a *prima facie* case of obviousness. See, *In re Fritch*, 972 F.2d 1266 (Fed. Cir. 1992).

Barbut '057 provide methods and apparatus for "protecting, perfusing, and optionally cooling the cerebral vasculature of a patient with oxygenated blood or other media" in circulatory arrest. See, column 1, lines 16-20. The occlusion balloons in Barbut '057 are provided to perfuse blood in an antegrade direction through the vessels to maintain oxygenation of the brain during cardiac arrest, not to aspirate emboli or inhibit antegrade flow. Barbut '370, on the other hand, is directed to devices and methods for redirecting flow from the internal carotid artery to the external carotid artery during treatment of a lesion in the internal carotid artery. One of ordinary skill would have perceived no value in modifying

catheter 1 of Barbut '057 according to catheter 12 of Barbut '370 to provide aspiration of emboli or to inhibit cerebral perfusion, since such a modification would have been contrary, or at most irrelevant, to the stated purpose of the Barbut '057 invention.

Moreover, while Barbut '370 is directed generally to emboli removal, it provides **no teaching** that inhibiting antegrade flow in the contralateral carotid artery or vertebral arteries would reduce emboli dispersion. Instead, Barbut '370 teaches the **desirability** of dispersing emboli into the external carotid artery. See Opening Brief at 12-13. The Examiner's Answer proffers no rationale as to why, when read in context, those disparate references would have motivated one of ordinary skill to have attempted to combine them, or how such combination should or could be accomplished. The Final rejection herein thus fails the threshold inquiry to establish a *prima facie* case of obviousness.

Further, since the goal of the Barbut '057 system is completely unrelated to that of the present invention, there would have been no expectation that the proposed combination would provide success in removing emboli during a thrombus removal procedure. To the contrary, the specific configuration of the catheter's in Barbut '057 would be unable to perform that function. Again, the Examiner's Answer proffers no basis to satisfy the second requirement for a *prima facie* case of obviousness.

And finally, as discussed hereinabove, even if Barbut '057 and '370 could somehow be combined or modified in view of each other, the resulting system still would not meet all of the limitations of the claims on appeal. Appellants' respectfully maintain that there is no motivation to combine Barbut '057 and

Barbut '370, and that the claims patentably distinguish over those references.

**IV. Barbut '057 and Barbut '370 are
Directed to Different Fields of Endeavor**

In response to appellants' argument that the Final rejection was based on hindsight gleaned from appellants' specification, the Examiner's Answer asserts that "so long as [the hindsight reasoning] takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." Notably, the principal references relied upon for the rejections herein have a common inventor and common assignee, but do not cite each other and have no cited prior art in common. These facts alone show that the references are directed to **unrelated** fields, and that the "reconstruction" here was based on hindsight, not the knowledge within the level of ordinary skill.

The Examiner's Answer asserts that Barbut '057 and Barbut '370 teach a system and catheter for "cerebral blood manipulation." As described at length in appellants' opening brief, the references are not directed to the "same field of endeavor," and cannot be properly combined.

In *In re Clay*, 966 F.2d 656, 658 (Fed. Cir.1992), the Federal Circuit reviewed denial of a patent on a process for storing refined petroleum "in a storage tank having a dead volume between the tank bottom and its outlet port." The application in issue there claimed a method for placing a solution in the dead volume and gelling the solution so that it substantially filled the dead volume. The application further was directed to a process for removing the gel by adding a hydrogen peroxide solution to the tank. *Id.* In reversing a

determination that a patent that disclosed a similar gel to reduce the permeability of natural hydrocarbon-bearing formations was within the "same field of endeavor," the Circuit held:

"The PTO argues that Sydansk [the alleged prior art reference] and Clay's inventions are part of a common endeavor - 'maximizing withdrawal of petroleum stored in petroleum reservoirs.' However, Sydansk cannot be considered to be within Clay's field of endeavor merely because both relate to the petroleum industry. Sydansk teaches the use of a gel in unconfined and irregular volumes within generally underground natural oil-bearing formations to channel flow in a desired direction; Clay teaches the introduction of gel to the confined dead volume of a man-made storage tank. The Sydansk process operates in extreme conditions, with petroleum formation temperatures as high as 115 degrees [centigrade] and at significant well bore pressures; Clay's process apparently operates at ambient temperature and atmospheric pressure. Clay's field of endeavor is the storage of refined liquid hydrocarbons. The field of endeavor of Sydansk's invention, on the other hand, is the extraction of crude petroleum. The Board clearly erred in considering Sydansk to be within the same field of endeavor as Clay's." *Id.* at 659.

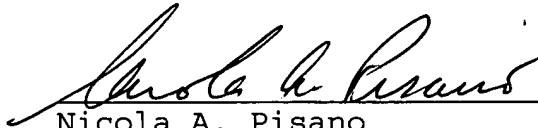
Id. As in *Clay*, where the Federal Circuit held that two processes were not within the same field of endeavor merely because both related to the petroleum industry, here *Barbut '057* and *Barbut '370* are not within the same field of endeavor merely because both patents relate to systems for "cerebral blood manipulation". The relevant inquiry is whether both systems are designed to solve the problem confronted by the inventor. See *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998) ("To ascertain the scope of the prior art, a court examines the field of the inventor's endeavor, and the particular problem with which the inventor was involved" (emphasis added)).

In the instant case, the inventions disclosed in Barbut '057 and Barbut '370 are directed to distinct and separate fields of endeavor, comprise distinctly different devices and are used for completely different purposes. As noted in Appellants' opening brief, the goal of Barbut '057 is to enhance perfusion of the cerebral vasculature to preserve brain tissue during circulatory arrest. On the other hand, Barbut '370 is directed to a device used to induce retrograde flow in the internal carotid artery during angioplasty of a carotid artery lesion. Even more than in *Clay*, the conditions under which the systems in Barbut '057 and '370 are employed are dissimilar (perfusion of the brain versus lesion repair; cardiac arrest versus beating heart, etc.), and the objectives to be achieved by the two systems are completely different. Because the principal references are not within the "same field of endeavor," the rejection cannot stand.

V. Conclusion

In view of the foregoing, appellants submit that the pending claims patentably distinguish over the prior art. Appellants respectfully request that the rejections under 35 U.S.C. § 103(a) be reversed and that the present application be passed to issue.

Respectfully submitted,



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